

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Applicant

Mary Katherine Robinson et al.

CRUNCHY CHEWING GUM

Serial No.

09/250,834

Filed

February 16, 1999

For

Examiner

Arthur L. Corbin

Art Unit

1761

Confirmation No.

2533

Attorney Docket No.

5079D1-07-LA

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: MAIL STOP PETITIONS, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450

ON___ NAME October 23, 2006 Jill S. Garretson

SIGNATURE

October 23, 2006

Mail Stop Petitions

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

DECLARATION IN SUPPORT OF CONCEPTION AND

REDUCTION TO PRACTICE OF INVENTION PRIOR TO JUNE 18, 1996

Dear Sir:

- I, Mary K. Robinson, declare and say as follows:
- 1. I am one of the principal inventors of the subject matter of the aboveidentified patent application U.S. Serial No. 09/250,834 filed February 16, 1999. It is

ARK:jsg091406/1901046.DEC-MKR

my understanding that the present application claims priority benefits of U.S. Serial No. 08/806,969 filed February 26, 1997.

- 2. Based on information and belief, the claims of the present application are directed to a crunch providing ingredient suitable for incorporation internally into a chewing gum. The claims provide that the crunch providing ingredient is a granulated additive consisting essentially of isomalt having a particle size greater than 50 mesh. The claims also require that the isomalt is prepared by a process wherein the isomalt is heated at a temperature above 130°C and cooled to form a solid isomalt product which is then granulated to the desired particle size.
- 3. Attached to this Declaration as Exhibit A is a document entitled, "Invention Record" identified by a corporate internal code system as IR No. 2583. The document was prepared by me or under my supervision and control and describes the invention at that time as using polyols including Palatinit to produce a "crunch" material similar to granulated sugar for use in a chewing gum composition identified in the Invention Record as "Burst" gums. The document was prepared on or shortly before the date appearing on the document (April 29, 1994) which is the date the document was submitted to the Patent Department of Warner-Lambert Company as was the customary corporate procedure.
- 4. The Invention Record further states that the "crunch" material has comparable stability data to granulated sugar. The Invention Record cites Notebook

No. 16969 (hereinafter "Notebook") and various pages of the Notebook describing experiments conducted by me or under my supervision and control testing the various crunch materials mentioned in the Invention Record including Palatinit.

- 5. It was the customary procedure of Warner-Lambert Company to provide consecutively numbered Notebooks for the concurrent recordation of laboratory experiments and observations. The pages of the Notebook listed in Exhibit A describing the experiments are pages 41-43, 47, 54, 66, 68 and 69 which are dated from May 6, 1993 to February 25, 1994. True copies of these Notebook pages are included herein as Exhibit D. Based on information and belief, the Invention Record accurately reflects the dates the experiments were conducted.
- 6. Palatinit is a well known tradename for isomalt. Exhibit A bears my signature and execution date of May 11, 1994 which was witnessed on the same day by Michael Glass, another inventor of the subject matter of the present application. Signing and witnessing of Invention Records was a customary procedure at Warner-Lambert Company.
- 7. Attached to this Declaration as Exhibit B is a document entitled, "Memorandum" prepared by me for Linda Vag, a Patent Agent employed at the time of this Memorandum by Warner-Lambert Company. The document is dated July 14, 1994 and represents the date the Memorandum was prepared and/or completed. Warner-Lambert Company is the predecessor owner of the subject matter of the

present application in which the Adams Division of Warner-Lambert Company was purchased by the current owner Cadbury Adams USA LLC. The Memorandum was submitted to the Warner-Lambert Company Patent Department as was a customary procedure at Warner-Lambert Company and bears the "received" stamp of the Warner-Lambert Company Patent Department dated August 8, 1994.

- 8. The Memorandum is a detailed description of the experimental work and observations performed as recorded in the Notebook 16969 and the pages referred to in paragraph 5 herein.
- 9. The Memorandum was prepared by me or under any direct supervision and control and was prepared in accordance with a customary procedure at Warner-Lambert Company for providing details of experimental work to the Patent Department for consideration of the filing of a patent application. The Memorandum shows that after initial testing Palatinit (isomalt) provided a long lasting crunch material suitable for incorporation into a chewing gum product. The Description of Invention section indicates that initial attempts to use sorbitol and mannitol were unsuccessful because they did not recrystallize. Xylitol and Palatinit (isomalt) remained the operable crunch materials. The Memorandum indicates that the first application of the use of Palatinit as a sugarless crunch material was conducted on May 6, 1993 and refers to Notebook No. 16969, pages 41-43 (see Exhibit D) which coincides with the Notebook and page entries appearing in Exhibit A. There is described in this section of Exhibit B an experiment in which a Palatinit solution was

heated to a temperature of 160°C which is above the 130° minimum temperature recited in the claims of the present application (see Exhibit D, page 42). It is indicated on the second page of the Memorandum that desirable results were achieved. After heating, the Palatinit solution was poured onto a metal tray (aluminum pan) and cooled at room temperature as required in the present claims. The cooled product was a solid isomalt product which was then granulated through a particular sieve to obtain particle sizes ranging from 30 mesh to 40 mesh which are particle sizes greater than 50 mesh (see Exhibit D, bottom of page 42). A particle size of 50 mesh is equivalent to a particle size of 0.300 mm. A particle size of 40 mesh is equivalent to a particle size of 0.425 mm. A particle size of 30 mesh is equivalent to a particle size of 0.600 mm. Thus, a particle size in the range of 30 mesh to 40 mesh covers particle sizes greater than 50 mesh.

- 10. The Palatinit solution prepared as described above contained 100% Palatinit and no other additives. Thus, the initial solution which contains 70% Palatinit and 30% water constituted the only two ingredients in the Palatinit solution and removal of water resulted in a raw material containing only Palatinit.
- 11. Tables I and II of the Memorandum show material stability tests for the Palatinit raw material and the 70% solution of Palatinit. The results of such tests show excellent stability with very little moisture pick up over the course of five weeks making the resulting material suitable as a crunch material.

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- 12. Table III shows a stability test wherein granular Palatinit prepared in accordance with Notebook No. 16969, page 43 was heated to 160°C, cooled and hardened and screened to produce particle sizes of from 30 mesh to 40 mesh. Stability test results show excellent stability and little change in water content over the course of five weeks making the resulting material suitable as a crunch material.
- 13. Table IV shows the testing of lab batches of sugarless gum containing Palatinit as a crunching agent identified as Batch No. 3-0725 which was made on May 28, 1993 and is referenced on page 47 of the Notebook 16969. The gums were evaluated to determine the amount and duration of crunch. The results are shown in Table IV. The gums exhibited a consistent crunch for two minutes which gradually diminished over a five minute chew.
- 14. The same gums (Batch No. 3-0725) were evaluated for stability in a twelve week accumulated aging process. The results shown in Table V of the Memorandum and page 47 of the Notebook 16969 indicate acceptable stability. Acceptable crunch and stability is also shown for samples of chewing gum containing Palatinit identified as Batch No. 4-0146 and 4-0148. These batches were produced on February 23, 1994 (see Exhibit D, bottom of page 66). Acceptable stability is shown for these batches by the results shown in Tables VI and VII (see Exhibit D, page 69).

- 15. An additional sample of gum containing Palatinit (Batch No. 4-0191) was prepared by the process described in Notebook No. 16969, page 69 on March 14, 1994 using Palatinit crystal made on March 8, 1994 as described on page 68 of the same Notebook. Tables VIII shows stability of the gum in connection with moisture pick up and Table IX shows stability of the gum in an accelerated aging process (see Exhibit D, page 69). Both test results indicate acceptable stability.
- 16. Attached hereto as Exhibit C are details of the formulation and process of preparation for Batch No. 4-0191 which is the same chewing gum batch tested in connection with Tables VIII and IX of Exhibit B (see paragraph 15). Exhibit C shows that chewing gum contained a polyalcohol and particularly Palatinit. The Palatinit material was heated to 160°C cooled and then ground to a 30 mesh particle size.
- 17. The Invention Record (Exhibit A) does not refer to pages 70 and 75 of Notebook No. 16969. These pages are included in Exhibit D because they show that maltitol crystals when used in a chewing gum does not exhibit good long term crunch properties (see page 70). Page 75 shows batches of Palatinit crystals (Batch Nos. 4-04965A and 4-0495C) exhibited acceptable stability as measured by long term moisture pick up and accelerated aging.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false ARK:jsg091406/1901046.DEC-MKR

statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing

thereon.

Date: 9-27-2006

Mary Katherine Robinson

Mary Katherine Robinson

INVENTION RECORD

WARNER-LAMBERT COMPANY

	_Nating	(1-4)			583	
Date	Rating	(1-4)	Da		tted 4/29/	
Date	Rating Rating Rating	(1-4)	I		s) <u>M.Robins</u>	
					C. Krame	er
Fo	r Invention Com	mittee Use				
1.	TITLE: Sugarle:	ss Crunch				
2.	DESCRIPTION OF	NOVELTY OF I	INVENTION:			
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3.	ADVANTAGES OF	INVENTION:			•	
	Produce a "cruwith comparable	nch" materia e stability o	l for use lata to gr	in sugan anulated	rless burst sugar.	gums
4.	Lab. Notebook 1	No. <u>16969</u> Page	e(s)*	Lab l	Notebook Da	te <u>*</u>
	* pgs.41,42,43 pg. 54 Date pg. 68 Date	6/28/93 pc	r. 66 Date	e: 2/14/9	93	
5.	Has this been t	ried? Yes_	X No	_ In Pro	gress <u>X</u>	
6.	Prior art searc	ch? Yes_	No	_ In Pro	gress	_
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WARNER-LAMBERT COMPANY

Memorandum

Date: July 14, 1994

PD- 5079

Consumer Products Research & Development Gum Development

To:

Linda Vaq

From:

Mary Robinson

Subi:

PATENT MEMORANDUM-SUGARLESS CRUNCH

Inventors: Mary Robinson

Colleen Kramer Michael Glass

Statement of Invention:

The present invention pertains to a method of producing a long lasting crunch material from Palatinit PF (Isomalt). More particularly, this invention is directed towards providing a stable material which when incorporated into a gum formulation provides better crunch than granulated sugar presently used in the sugared "Burst" product line. The method of processing the above described material, is necessary to provide a stable material with a shelf life comparable to granulated sugar both as a raw material and as a crunch material in the gum formula. Prior art has not alluded to the use of Isomalt as an ingredient in a gum product to provide a crunch, therefore the material and the processing procedure used to produce the crunch material has not been alluded to in any prior art.

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Utility of Invention:

Invention has applicability in Sugared and Sugarless Gums for the U.S. and Canada.

Description of Invention:

Initial attempts involved the use of Sorbitol and Mannitol; independently and in combination. These materials when heated to 160C melted, but did not recrystallize upon cooling. These two materials were then eliminated as a possible source for crunch material. Subsequent experiments centered on the use of Xylitol and Palatinit PF (Isomalt). The first application on the use of Xylitol and Palatinit PF, as a sugarless crunch material, was conducted on May 6, 1993, with the description of the procedure to be used. (Notebook #16969, Pages 041, 042, and 043). Initially a 70% solution was made using Xylitol at 70% and 30% water and a second solution using 70% Palatinit PF and 30% water. The Xylitol solution was brought to a temperature of 120C and a sample was taken to determine when crystallization takes place. While Xylitol did crystallize at 120C, the solution continued to be heated to 130C, 140C, 150C and 160C respectively and samples taken at each temperature range to determine optimum temperature for desired crystalline

structure. The Palatinit PF solution was heated to 160C at the onset and produced the desired results. The solutions were poured onto a metal tray and cooled at room temperature for eighteen hours. The cooled and hardened Xylitol and Palatinit PF solutions were then screened through a #20 Sieve and particle sizes ranging from #30 mesh to #40 mesh were produced and stability studies conducted.

The next step was to conduct a material stability test, comparing the raw material Xylitol and Palatinit PF to the processed material. The raw material and the processed material were placed in 80F/80RH incubator for five weeks to conduct moisture pick-up studies. Table I contains the stability data for the raw material starting on May 10, 1993 and concluding on June 14, 1993. Table II contains the stability data for the processed material started on May 10, 1993 and concluded on June 14, 1993.

TABLE I:

Raw Material	Initial Weight* 5/10/93	Week 1 %	Week 2 %	Week 3 %	Week 4 %	Week 5 %
100% Palatinit PF MS#805A763	5.00	+1.4	+1.8	+2.2	+2.2	+2.4
100% Xylitol MS#A19A831	5.02	+0.6	+1.6	+6.4	+6.4	+3.5

^{*-}Weight in Grams; % = moisture pickup.

TABLE II:

Processed Material 70% Solution	Initial Weight* 5/10/93	Week 1 %	Week 2 %	Week 3 %	Week 4	Week 5 %
Palatinit MS#805A763	5.00	+1.4	+1.8	+2.2	+2.2	+2.4
Xylitol MS#A19A83	5.04	+0.6	+1.4	+6.0	+6.0	+3.5

^{*-}Weight in Grams; % = moisture pickup.

The next step was to melt Xylitol and Palatinit PF without using a solution. Powdered Xylitol and Granular Palatinit PF were used. (Notebook #16969, pg. 43). The Xylitol and the Palatinit PF were heated to 160C, poured onto cooling sheet and allowed to harden for twenty-four hours. The materials were then screened through a #20 Sieve to particle sizes ranging from #30 mesh to #40 mesh and stability studies were conducted on five gram samples.

TABLE III:

Processed Material @ 100%	Initial Weight* 5/19/93	Week 1 %	Week 2 %	Week 3 %	Week 4 %	Week 5 %
Palatinit MS#805A763	4.97	+4.3	+5.0	+5.0	+5.0	+4.8
Xylitol MS#A19A831	5.01	+3.9	+6.6	+4.1	+3.0	+2.5

^{*-}Weight in Grams; % = Moisture pickup.

The next step was to produce lab batches of sugarless gum using 10% Xylitol and Palatinit PF as a crunching agent. Batch # 3-0725 (Palatinit PF), Batch #3-0727 (Xylitol) were made on May 28, 1993; (NB #16969, Pg 47). The gums were subjected to evaluation to determine amount and duration of crunch. Four (4) Gum development colleagues conducted chew evaluations. Evaluations determined the following: Batch # 3-0725 (Palatinit) produced a popping type crunch which remained consistent for two minutes and diminished during a five minute chew. Batch # 3-0727 (Xylitol) produced a good initial crunch lasting for ninety seconds. Samples of these gums were placed into an 80F/80RH incubator to detect moisture pick-up over a five week period. Table IV reflects the results.

TABLE IV:

Batch No.	Initial Weight* 6/11/93	Week 1 % Change	Week 2 % Change	Week 3 % Change	Week 4 % Change	Week 5 % Change
3-0725 Palatinit	2.69	+18.3	+23.0	+22.5	+22.3	+22.5
3-0727 Xylitol	2.72	+17.6	+22.6	+22.8	+22.8	+23.2

^{*-}Weight in Grams; % = moisture pickup.

Gum samples were also placed in a 37C stability oven to evaluate the gums during a twelve week accelerated aging process. Table V indicated the results obtained when gums were chewed at two week intervals.

TABLE V:

Batch No.	Initial Chew	Week 2 6/25/93	Week 4 7/9/93	Week 6 7/23/93	Week 8 8/6/93	Week 12 9/3/93
3-0725 Palatinit	2:30	2:20	1:55	1:35	1:00	0:45
3-0727 Xylitol	1:30	1:30	1:30	1:30	0:50	0:40

NOTE: Numbers stated indicate duration of crunch in minutes and seconds.

On February 14, 1994 lab work resumed on the sugarless crunch project. Two batches of crunch material were made (NB 16969, Pg 66); one using Palatinit PF and another using Maltisorb Crystalline. The processed materials were then used in gum batches. The Maltisorb Crystalline material proved unsatisfactory. The Palatinit PF was used in Batch #4-0146 (Peppermint) and Batch #4-0148 (Cinnamon). Stability studies for moisture pick-up and crunch time were conducted. Table VI indicates 80F/80RH moisture pick-up study results and Table VII indicates 37C stability oven Chew/Crunch test results.

TABLE VI:

Batch No.	Initial Weight* 2/21/94	Week 1 % Change	Week 2 % Change	Week 3 % Change	Week 4 % Change	Week 5 % Change
4-0146	2.82	+15.9	+18.3	+21.9	+21.9	+22.5
4-0148	2.67	+18.6	+21.5	+21.5	+22.6	+22.6

^{*-}Weight in Grams; % = moisture pickup.

TABLE VII:

Batch No.	Initial Chew	Week 2 3/7/94	Week 4 3/21/94	Week 6 4/4/94	Week 8 4/18/94	Week 10 5/2/94	Week 12 5/16/94
4-0146	1:55	1:13	1:05	1:12	1:05	0:50	minimal
4-0148	3/1:53	1:40	0:51	1:02	0:50	minimal	minimal

NOTE: Numbers stated indicate duration of crunch in minutes and seconds.

To improve the crunch and stabilize the crunch time Batch # 4-0191 (NB 16969, Pg 69) was made on 3/14/94. The 15% Mannitol was removed from the gum formulation and replaced with 16% Palatinit crystals made in lab Batch # 4-0149 on 3/8/94, (NB 16969, Pg. 68). Table VIII indicates moisture pickup results and Table IX indicates the Chew results.

TABLE VIII:

Batch No.	Initial Weight* 3/14/94	Week 1 % Change	Week 2 % Change	Week 3 % Change	Week 4 % Change	Week 5 % Change
4-0191	2.81	+19.5	+24.9	+24.9	+24.9	+25.8

^{*-}Weight in Grams; % = amount of moisture pickup.

TABLE IX:

Batch No.	Initial	Week 2	Week 4	Week 6	Week 8	Week 12
	Chew	3/7/94	3/21/94	4/4/94	4/18/94	5/16/94
4-0191	1:51	1:51	1:51	1:51	1:20	1:00

NOTE: Numbers stated indicate duration of crunch in minutes and seconds.

Breadth of Coverage:

Ingredients as a percentage of Sugarless Crunch

<u>Ingredient</u> <u>Percentage</u>

Palatinit PF (Isomalt) 100%

Ingredients as a percentage of the finished product:

Formulation # 2 (4-0191):

Ingredients:	Percentage:
Gum Base	5-50%
Softeners	2-10%
Flavor(s)*	0.5-5%
Intense Sweeteners**	0-2%
Polyalcohois***	1-70%
Colorants****	0-1%

- * Flavors may be any flavor currently used in Burst on a global basis or flavors developed for future burst lines.
- ** Intense sweeteners may be any one of, or combination of Aspartame, Saccharin, Acesulfame-K, Sucralose, etc.
- *** Polyalcohols may be any one of, or combination of sorbitol, mannitol, xylitol, palatinit, etc.
- **** Colorants can be either dyes or lakes of any color deemed acceptable for the flavor it represents.

METHOD of APPLICATION:

Sugarless Crunch:

The Palatinit PF material is heated to 160C. The material is then cooled and ground to #30 particle size using Calcium Carbonate or Talc as a processing aid. In actual production and extruder will be used to heat, cool and grind the Palatinit PF.

Finished Product:

The processed Palatinit PF material is added to the gum kettle containing partially mixed gum ingredients and mixed until completion of full mixing cycle.

Prior Art Search:

A Patent search (attached) was conducted for chewing gum products using Palatinit PF as an internal crunching agent. The resultant search showed no patents using the described method of processing palatinit or using such a processed material as a crunching material in gum. References to Palatinit (Isomalt) refer to its use as a bulking agent and/or sugar replacement in baked goods and confections.

Timing for Filing:

The utility of this invention is being sought for sugarless gum line extensions to the burst line in the U.S. and Canada. Patent filing required prior to introduction of Palatinit PF, crunching agent, to Brand and Affiliates.

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